U.S. Department of Justice

John W. Vaudreuil
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October 12, 2016

Pamela L. Johnston
Foley & Lardner, LLP
555 South Flower Street, Suite 3500
Los Angeles, CA 90071-2411

Re: *United States v. NeuroScience, Inc.*

Dear Attorney Johnston:

This is the proposed plea agreement between the defendant and the United States in this case.

1. The defendant agrees to waive indictment and plead guilty to Count two of the information filed by the United States Attorney's Office. This count charges a violation of Title 18, United States Code, Section 371, which carries maximum penalties of a $500,000 fine, five years of probation, and a $400 special assessment. The defendant agrees to pay the special assessment at or before sentencing. The defendant understands that the Court will enter an order pursuant to 18 U.S.C. § 3013 requiring the immediate payment of the special assessment. In an appropriate case, the defendant could be held in contempt of court and receive an additional sentence for failing to pay the special assessment as ordered by the Court.

2. The defendant and United States agree that attached Exhibit A is an accurate factual basis for the plea to the charge.

3. Defendant shall provide to the United States Attorney's Office and the Court a copy of a resolution of the Board of Directors of NeuroScience, Inc., affirming that NeuroScience, Inc. has authority to enter into this plea agreement and that the Board has: (1) reviewed the Information in this case and the proposed plea agreement; (2) consulted with legal counsel in connection with the matter; (3) consented to enter into the proposed plea agreement; (4) authorized Defendant to plead guilty to the charge specified in the plea agreement; and (5) authorized Mieke Kellermann, Executive Vice President of NeuroScience, Inc., to execute the plea agreement and all other documents necessary to carry out the provisions of the plea agreement.

4. Mieke Kellermann, Executive Vice President, NeuroScience, Inc., agrees that she is an "authorized representative" of NeuroScience, Inc., and as such can legally bind defendant in this case. Further, Mieke Kellermann understands and agrees, pursuant to 18 U.S.C. § 3572(f), that she is an "individual authorized to make disbursements for the organization," and as such has a duty to pay, from the assets of the organization, any fine, special assessment, or other monetary obligation that is part of the sentence imposed upon NeuroScience, Inc.

5. The defendant acknowledges, by pleading guilty, that it is giving up the following applicable rights: (a) to plead not guilty and to persist in that plea; (b) to a jury trial; (c) to be represented by counsel--and if necessary have the Court appoint counsel--at trial and at every other stage of the trial proceedings; (d) to confront and cross-examine adverse witnesses; (e) to testify and present evidence; and (f) to compel the attendance of witnesses.

6. The defendant acknowledges, after consultation with its attorney, that it fully understands the extent of his rights to appeal the conviction and sentence in this case. By the signature of Mieke Kellermann below, the defendant knowingly and voluntarily waives all rights, including those conferred by 18 U.S.C. § 3742, to appeal the conviction and any sentence, including any issues with respect to the reasonableness of the sentence imposed.

7. The United States agrees to recommend that the Court, in computing the advisory Sentencing Guideline range, and in sentencing the defendant, give the defendant the maximum available reduction for acceptance of responsibility. This recommendation is based upon facts currently known to the United States and is contingent upon the defendant accepting responsibility according to the factors set forth in USSG § 8C2.5(g)(2). Further, the United States' agreement to recommend a reduction for acceptance of responsibility is also based on the defendant providing a full and truthful accounting in the required financial statement. The United States is free to withdraw this recommendation if the defendant has previously engaged in any conduct which is unknown to the United States and is inconsistent with acceptance of responsibility, or if the defendant engages in any conduct between the date of this plea agreement and the sentencing hearing which is inconsistent with acceptance of responsibility.

8. The United States agrees that this guilty plea will completely resolve all possible federal criminal violations that have occurred in the Western District of Wisconsin provided that both of the following conditions are met: (a) the criminal conduct relates to the conduct described in the information; and (b) the criminal

conduct was known to the United States as of the date of this plea agreement. This agreement not to prosecute is limited to those types of cases for which the United States Attorney's Office for the Western District of Wisconsin has exclusive decision-making authority. The defendant also understands that the United States will make its full discovery file available to the Probation Office for its use in preparing the presentence report.

9. The defendant agrees to complete the enclosed financial statement and return it to this office within two weeks of the guilty plea hearing. The defendant agrees that this financial statement will be a full and truthful accounting, including all available supporting documentation. The defendant also authorizes the U.S. Attorney's Office to run the defendant's credit report. The defendant also agrees that the probation office may disclose to the United States the net worth and cash flow statements to be completed by the defendant in connection with the preparation of the presentence report, together with all supporting documents. Finally, the defendant understands, as set forth in Paragraph 7 above, that the United States' agreement to recommend a reduction for acceptance of responsibility will be based, in part, on the defendant's full and truthful accounting.

10. In the event of an appeal, the United States reserves the right to make arguments in support of or in opposition to the sentence imposed by the Court.

11. The defendant understands that sentencing discussions are not part of the plea agreement. The defendant should not rely upon the possibility of a particular sentence based upon any sentencing discussions between defense counsel and the United States.

12. If your understanding of our agreement conforms with mine as set out above, would you and the defendant please sign this letter and return it to me. By Mieke Kellermann's signature below, the defendant acknowledges its understanding that the United States has made no promises or guarantees regarding the sentence which will be imposed. The defendant also acknowledges its understanding that the Court is not required to accept any recommendations which may be made by the United States and that the Court can impose any sentence up to and including the maximum penalties set out above.

13. By your and Mieke Kellermann's signatures below, you and the defendant also acknowledge that this is the only plea agreement in this case.

Very truly yours,

JOHN W. VAUDREUIL
United States Attorney

By:

ANTONIO M. TRILLO
Assistant United States Attorney

10/12/16
Date

PAMELA L. JOHNSTON
Attorney for the Defendant

10-13-16
Date

NEUROSCIENCE INC.
BY: MIEKE KELLERMANN
Defendant

10.12.16
Date

Enclosure

Exhibit A

Since at least 2009, NeuroScience, Inc. ("NeuroScience") has been a Wisconsin Corporation providing healthcare providers with assessments of laboratory tests and nutritional supplements. NeuroScience operates within the Western District of Wisconsin. Gottfried Kellermann ("Kellerman") was the founder and Chief Executive Officer of NeuroScience. Kellermann was also the founder of a laboratory associated with NeuroScience (the "Laboratory"). The Laboratory also operates within the Western District of Wisconsin, and it has been an independent, reference laboratory certified under the Clinical Laboratory Improvement Amendments ("CLIA") since at least 2008.

The CLIA program certifies laboratories to provide certain laboratory services for which certification is required under CLIA. The Centers of Medicare and Medicaid Services ("CMS"), a federal agency and component within the United States Department of Health and Human Services, administers the CLIA program.

In order to provide laboratory services as an independent, reference laboratory, a laboratory is required to apply for an obtain a Certificate of Compliance from the CLIA program. Laboratories must reapply for a Certificate of Compliance every two years. The CLIA program will issue a certificate of compliance to a laboratory only if the laboratory meets the requirements of, among others, subparts C, H, J, K, M, and Q of Title 42, Code of Federal Regulations, Part 493. Title 42, Code of Federal Regulations, Part 493 contains regulations promulgated under CLIA.

CLIA regulations require that for all laboratory-developed tests, a CLIA certified laboratory must establish performance specifications for accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference intervals, and any other performance characteristic required for test performance. This is commonly referred to as "method validation" or "validation studies." Method validation assures that a laboratory-developed test consistently reports accurate and reliable results.

Laboratories issued Certificates of Compliance are subject to announced and unannounced inspections by CLIA, in part for CLIA to determine if laboratories are in compliance with CLIA regulations. If a laboratory is found to not be in compliance, the laboratory is required to submit a plan of correction detailing how it intended to come into compliance with CLIA requirements.

During the period alleged in the information, the Laboratory applied for, obtained, and maintained a Certificate of Compliance from CLIA to provide laboratory services for diagnostic immunology, chemistry, and hematology specialties. The Certificate of Compliance allowed the Laboratory to provide laboratory services known as "neurotransmitter testing." Neurotransmitters are chemical messengers that the human body uses to communicate between the brain and other parts of the body. For neurotransmitter testing, the Laboratory tested urine specimens for the quantification of certain neurotransmitters, e.g., Dopamine, Epinephrine, or NorEpinephrine. These tests were subject to CLIA regulations applicable to laboratory-developed tests.

NeuroScience created reports for healthcare providers, who in turn used them as part of the treatment provided to their patients. The Laboratory, in discussions with NeuroScience, developed a range to report results as elevated or decreased. The Laboratory entered the range into the Laboratory Information Management System. The Laboratory performed neurotransmitter tests on patient samples and entered the results of the tests into its Laboratory Information Management System. NeuroScience then used the laboratory test results to recommend its and other nutritional supplements to healthcare providers.

The Laboratory also accepted specimens from patients in New York. The New York Department of Health regulated the Laboratory's testing of such specimens. New York rules also required that for laboratory-developed tests, the Laboratory establish performance specifications for accuracy, precision, reportable range of results, reference intervals, analytical sensitivity and specificity, and other applicable performance characteristics.

On or about March 5, 2009, the Laboratory's regulatory affairs manager emailed Kellermann with the subject "Design, Verification, and Validation," advising Kellermann that the Laboratory needed to perform a "validation study before using [a] method in clinical lab, and that [this] is the rule for CLIA as well as for New York State." In particular, she advised that the Laboratory's studies needed to encompass "accuracy," or "the degree of closeness of a measured or calculated quantity to its actual (true) value," "precision," or "how close together or repeatable the results are," and "reference intervals (normal value[s])."

Then on or about March 17, 2009, the same regulatory affairs manager emailed Kellermann and enclosed a document entitled "For CLIA As Well As New York/DOH," which explained that the Laboratory "need[ed] validation studies done before reporting patient results" for laboratory-developed tests, and that in order to comply with CLIA regulations and New York State regulations, the Laboratory was required to validate through a study the accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and normal (reference) range. Additionally, for New York, the Laboratory had to complete a comparison with a reference method and any evaluation of bias, and needed to submit all the data to get written approval from New York's Department of Health.

From at least April 2011 through February 2014, NeuroScience used a narrowed range to report neurotransmitter test results as elevated or decreased. This narrowed range was sometimes called "optimal" range, and it was narrower than the reference range defined by CLIA regulations. CLIA regulations define the reference range of values used in reports as 95 percent of individuals who are presumed to be healthy. Although the Laboratory validated the reference ranges for its neurotransmitter tests, Kellermann and the Laboratory did not establish the validity for the additional narrowed ranges used in the reports, that is, the narrowed ranges were not validated pursuant to CLIA regulations.

In late 2009 or early 2010, the Laboratory submitted an application package to the State of New York's Department of Health seeking permission to test certain specimens from New York, including a Dopamine neurotransmitter test. New York has opted out of CLIA and requires laboratories that want to conduct tests on New York-based specimens to be separately certified and regulated solely by the New York Department of Health. In response to the Laboratory's application, on March 5, 2010, New York state regulators sent a letter to Kellermann requesting further information regarding the Laboratory's application to conduct certain neurotransmitter testing on New York resident specimens. New York regulators stated in their March 5, 2010, letter that an "optimal range may be included in reports provided supporting validation studies are submitted and approved; specifically you must minimally describe how the optimal range is defined and identified, how it differ from a reference range, and provide evidence that it is accepted by experts in the field other than yourself."

On or about August 9, 2010, Kellermann responded to further correspondence from New York stating, "Indeed these urine neurotransmitter tests are difficult to validate based on currently established criteria by your department. Although I am quite familiar with the department's regulation we found it difficult to provide the correct data for the validation of neurotransmitter testing."

NeuroScience continued to use the narrowed range for neurotransmitter testing to report patient results as elevated or decreased through February 2014, and the Laboratory failed to disclose the use of this procedure to CLIA inspectors. The Laboratory also failed to disclose to CLIA inspectors that New York regulators notified the Laboratory that it could not use the narrowed ranges without first validating the ranges.

On March 19, 2012, after CLIA learned that the Laboratory had not validated another type of testing, the Laboratory represented: "Additionally, we will diligently revisit all our lab procedures regardless whether they were brought to our attention or not to make sure they meet CLIA guidelines." After March 19, 2012 and continuing through February 2014, the Laboratory did not establish the validity of its neurotransmitter testing to include NeuroScience's use of a narrower range than is defined by CLIA regulations, and it did not notify CLIA of this.

During the time period alleged in the Information, the following acts were committed:

- On March 16, 2010, Kellermann submitted a CMS-116 Form to the CLIA program on behalf of the Laboratory. The form certified that the Laboratory would operate in accordance with standards set by the Department of Health and Human Services.

- On December 28, 2011, a Laboratory research and development employee sent an email to employees of the Laboratory and NeuroScience adopting narrowed ranges used by NeuroScience for neurotransmitter testing.

- On March 7, 2013, a Laboratory research and development employee sent an email to employees of the Laboratory and NeuroScience adopting narrowed ranges used by NeuroScience for neurotransmitter testing.